

REMARKS

In the office action mailed July 18, 2003, the Examiner rejected claim 52 under 35 U.S.C. §112, first paragraph. Claims 25-27, 31-33, and 52 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,957,949 to Leonhardt in view of U.S. Patent No. 5,411,552 to Andersen. Applicants respectfully request reconsideration of the application in view of the following comments.

Rejection Under 35 U.S.C. §112

In the office action, the Examiner rejected claim 52 under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. Claim 52 recites that the flow control device additionally comprises a frame coupled to the valve body. The Examiner asserted in paragraph 2 of the office action, that "the specification does not support the frame being coupled ("defined as "linked" or "connected") to the valve body."

Applicants respectfully disagree. Merriam-Webster's Collegiate Dictionary provides several definitions for the word "coupled", including "to connect for consideration together", "to join for combined effect", and "to fasten together." (See excerpt from Merriam-Webster's Collegiate Dictionary, Tenth Edition, attached hereto as Exhibit A.) The specification provides support for the frame being "coupled" to the valve body under any of the foregoing definitions. Figures 1 and 2 of the specification, for example, show one possible embodiment of a flow control device where the valve body 24 is coupled to the frame 30 via a valve support 22. The valve support 22 provides a connection or a link between the valve body 24 and the frame 30. Although the valve body 24 and frame 30 are not directly contacting one another in Figures 1 and 2, Applicants note that

the foregoing definitions do not require direct contact between two elements.

Thus, the frame 30 is shown "coupled" to the valve body 24 in Figures 1 and 2.

Figure 8 shows another embodiment of the flow control device wherein the frame is coupled to the valve body and directly contacts the valve body. As described in the last paragraph of page 7 (which extends through page 8) of the specification, Figure 8 shows a conically shaped portion 50 of the frame 46, which provides a passageway 52 for operation of the valve mechanism. As stated on page 8, lines 7-8, the "valve body 56 [of the frame 46] extends across the passageway 52." Thus, Figure 8 and the corresponding description describe another embodiment of a flow control device where the frame is coupled to the valve body, thereby providing further support for claim 52.

In support of the rejection of claim 52 under Section 112, the Examiner stated that "on page 6, lines 9-16 [of the specification], applicant teaches opposite of this claim limitation, specifically that a cylindrical element 36 between disk elements 38, 40 is used to separate the valve body from the seal, within which the frame is located." The examiner seems to imply that the use of the word "coupled" to describe two items precludes the two items from being separated by an intermediate item. However, the definitions of the word "coupled" do not provide such a preclusion and the examiner has provided no support for such an interpretation of the word "coupled." Thus, the description at page 6, lines 9-16, which describes an intermediate structure between the frame and valve body, is in no way at odds with the frame being "coupled" to the valve body.

The examiner further stated that "[t]he specification teaches separating the valve body and the frame so that the valve body will not be distorted when the

frame expands." As discussed, use of the word "coupled" to describe two items does not preclude the two items from being physically separated, as it is still possible for the two items to be indirectly connected by an intermediate item. Nor does the use of the word "coupled" to relate the frame to the valve body indicate one way or the other whether the frame expansion distorts the valve body. Thus, although claim 52 recites that the frame is coupled to the valve body, the claim is silent as to whether or not the frame expansion distorts the valve body. Consequently, the use of the word "coupled" to relate the frame to the valve body is in no way opposite the description in the specification.

In view of the foregoing, applicants respectfully submit that the rejection of claim 52 under Section 112 should be withdrawn.

Rejection Under 35 U.S.C. §103(a)

Claims 25-27, 31-33, and 52 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,957,949 to Leonhardt in view of U.S. Patent No. 5,411,552 to Andersen. However, Applicant respectfully submits that the claims recite subject matter that is neither taught nor suggested by either Leonhardt or Andersen, both alone and in combination. For example, independent claim 25 recites the steps of placing in a pulmonic passageway a flow control device which has a resilient seal secured to a valve body. Both Leonhardt and Andersen fail to teach or suggest a flow control device which has a resilient seal. Accordingly, Applicants respectfully submit that the rejection of claims 25-27, 31-33, and 52 should be withdrawn.

Leonhardt describes a valve stent 20 comprised of three elements, including a stent 26, a biological valve 22, and graft material 24. In paragraph 4 of the office action, the examiner asserted that the graft material 24 corresponds

to the "resilient seal" of claim 25. However, unlike the resilient seal recited in claim 25, the graft material 24 is not resilient. Leonhardt describes the graft material 24 at column 5, lines 53-61, stating that the graft material 24 "is a thin-walled biocompatible, flexible and expandable, low-porosity woven fabric, such as polyester or PTFE." Nowhere in this description nor in any other part of the specification does Leonhardt state or even imply that the graft material 24 can be a resilient material. Indeed, at column 5, lines 59-61, Leonhardt states that the graft material 24 is tapered in order to prevent bunching of the graft material once placed in the patient. It is unlikely that a resilient material would bunch, as a resilient material would have the ability to recover its shape after deformation. This indicates that the graft material of Leonhardt is not resilient.

Rather than showing a graft material that is resilient, Leonhardt indicates that the graft material 24 is a material that passively conforms to the shape of the stent 26 to which it is attached. For example, Leonhardt describes at column 5, line 62 through column 6, line 8 how the graft material is attached to the stent 26 so that the material conforms tightly to the stent. Any resilient characteristics of the Leonhardt valve stent are provided solely by the stent 26, which is formed of a nitinol wire having superelastic characteristics. Leonhardt provides no suggestion or motivation for modifying the graft material to be resilient.

Andersen also fails to teach or suggest a flow control device which has a resilient seal that seals with a wall of a pulmonic passageway. Andersen describes a valve prosthesis for implantation in the body. The valve prosthesis includes a tubular means 24 having a cylinder surface that secures the valve prosthesis in a body channel by abutting the body channel. Anderson never shows that the tubular means is a resilient material. Rather, Andersen simply

states that the cylinder surface is closed by a "suitable material." See Andersen, col. 4, lines 3-5. Moreover, Andersen has no suggestion or motivation to make the cylinder surface a resilient material. In view of the foregoing, the rejection of claim 25 under 35 U.S.C. §103(a) should be withdrawn.

Claims 26-27, 31-33, and 52 depend from claim 25 and all of these claims recite subject matter that is neither taught nor suggested by the cited art. In addition, these claims are patentable in view of their dependence on claim 25.

If the Examiner has any questions regarding the foregoing, she is cordially invited to contact the undersigned so that any such matters may be promptly resolved.

Respectfully submitted,
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EXHIBIT A



Merriam-Webster's Collegiate[®] Dictionary

TENTH EDITION

Merriam-Webster, Incorporated
Springfield, Massachusetts, U.S.A.



A GENUINE MERRIAM-WEBSTER

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